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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,589	12/15/2003	Serengulam V. Govindan	40923-0004US1	2607

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EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,589	GOVINDAN, SERENGULAM V.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-62 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Govindan, Serengulam

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4 and 9-50, as specifically drawn to an immunoconjugate comprising a targeting moiety, a chemotherapeutic moiety and a linker binding to the targeting moiety via a thiol group, and to the chemotherapeutic moiety via an intraceullarly-cleavable moiety, wherein the intracellular moiety is an ester moiety, classified in class 530, subclass 391.7.

II. Claims 1, 5 and 9-50, Claims 1-4 and 9-50, as specifically drawn to an immunoconjugate comprising a targeting moiety, a chemotherapeutic moiety and a linker binding to the targeting moiety via a thiol group, and to the chemotherapeutic moiety via an intraceullarly-cleavable moiety, wherein the intracellular moiety comprises a peptide bond cleavable by intracellular enzymes, classified in class 530, subclass 391.7.

III. Claims 1 and 6-50, as specifically drawn to an immunoconjugate comprising a targeting moiety, a chemotherapeutic moiety and a linker binding to the targeting moiety via a thiol group, and to the chemotherapeutic moiety via an intraceullarly-cleavable moiety, wherein the intracellular moiety comprises an ether bond which is susceptible to cleavage under the acidic pH of intracellular compartments, classified in class 530, subclass 391.7.

IV. Claims 51 in part, 52 and 58-62, as specifically drawn to a method of treating a malignancy, wherein the malignancy is a malignant solid tumor or hematopoietic neoplasm, classified in class 424, subclass 181.1.

V. Claims 51 in part, 53-55 and 58-62, as specifically drawn to a method of treating an infection or infectious lesion, classified in class 424, subclass 181.1.

VI. Claims 51 and 57-62, as specifically drawn to a method of treating an autoimmune disease, classified in class 424, subclass 181.1.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-III represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. In the instant case, the immunoconjugate comprising a targeting moiety, a chemotherapeutic moiety and a linker binding to the targeting moiety via a thiol group, and to the chemotherapeutic moiety via an intraceullarly-cleavable moiety, wherein the intracellular moiety is an ester moiety (Group I), the immunoconjugate comprising a targeting moiety, a chemotherapeutic moiety and a linker binding to the targeting moiety via a thiol group, and to the chemotherapeutic moiety via an intraceullarly-cleavable moiety, wherein the intracellular moiety comprises a peptide bond cleavable by intracellular enzymes (Group II) and the immunoconjugate comprising a targeting moiety, a chemotherapeutic moiety and a linker binding to the targeting moiety via a thiol group, and to the chemotherapeutic moiety via an intraceullarly-cleavable moiety, wherein the intracellular moiety comprises an ether bond which is susceptible to cleavage under the acidic pH of intracellular compartments (Group III) are all structurally and/or chemically and/or functionally distinct compounds such that one invention could not be interchanged with the other. For example, it appears that each of the immunoconjugates comprise different intracellularly cleavable moieties such that one would not be cleaved in the others conditions. As such, each invention would require different searches and the consideration of different patentability issues. For these reasons, the inventions of Groups I-III are patentably distinct.

The inventions of Groups IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the

specification does not disclose that their methods would be used together. The method of treating a malignancy, wherein the malignancy is a malignant solid tumor or hematopoietic neoplasm (Group IV), the method of treating an infection or infectious lesion (Groups V), the method of treating an autoimmune disease (Group VI) are unrelated as they are directed as three morphological different disorders such that the population to be treated with be different. As such, it would be burdensome to search the inventions of Groups IV-VI. Therefore, the inventions of Groups IV-VI are patentably distinct.

The inventions of Groups I-III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of treating a malignancy, wherein the malignancy is a malignant solid tumor or hematopoietic neoplasm can be practiced with another materially different product such an immunoconjugate comprising an intracellularly cleavable ester moiety, an immunoconjugate comprising an intracellularly cleavable peptide bond or an immunoconjugate comprising an intracellularly cleavable ether bond.

The inventions of Groups I-III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of treating an infection or infectious lesion can be practiced with another materially different product such an immunoconjugate comprising an intracellularly cleavable ester moiety, an immunoconjugate comprising an intracellularly cleavable peptide bond or an immunoconjugate comprising an intracellularly cleavable ether bond.

The inventions of Groups I-III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product

or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of treating an autoimmune disease can be practiced with another materially different product such an immunoconjugate comprising an intracellularly cleavable ester moiety, an immunoconjugate comprising an intracellularly cleavable peptide bond or an immunoconjugate comprising an intracellularly cleavable ether bond.

Because the inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Species Election

This application contains claims directed to the following patentably distinct species of the claimed invention:

Claims 14 and 31, Groups I-III, are generic to a plurality of disclosed patentably distinct species comprising the following aminopolycarboxylate residues: DPTA, EDTA, ... TETA and N,N'-dialkyl substituted piperazine which differ at least in chemical formula and structure.

Claims 15 and 34, Groups I-III, are generic to a plurality of disclosed patentably distinct species comprising the following chemotherapeutic moieties: doxorubicin, epirubicin, morpholinodoxorubicin, ... ansamycins and epothilones which differ at least in chemical formula, structure and mechanism of action.

Claims 23, 24, 42, 43, 59 and 60, Groups I-VI, are generic to a plurality of disclosed patentably distinct species comprising the following antigens: B-Cell lineage, T-cell lineage, myeloid lineage, HLA-DR, CD74, CD22, ... prostate specific membrane antigen, ... 66CDd (CCM1) and anti-TAC which differ at least in where they are found and the morphological tissue/disorder which that are associated with.

Claims 25, 26, 44-47 and 61-62, Groups I-VI, are generic to a plurality of disclosed patentably distinct species comprising the following targeting moieties: LL1, LL2, hA20, ... CC49 and Immu 31 which differ at least in chemical structure, function and what they target.

Claims 54 and 55, Groups V, are generic to a plurality of disclosed patentably distinct species comprising the following pathogens: bacterium, fungus, virus, richettsia, mycoplasma and protozoa which differ at least in morphology such that one would not be obvious over the other.

Claim 57, Group VI, is generic to a plurality of disclosed patentably distinct species comprising the following class III autoimmune diseases: immune-mediated thrombocytopenias, dermatomyositis, ... rapidly progressive glomerulonephritis and fibrosing alveolitis which differ at least in morphology such that one would not be obvious over the other.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
9/6/05